K001242

JUL 1 3 2000

April 15, 2000

Applicant:

Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, PA 19040
Reg. No: 2510954

Contact Person:

James G. Carpenter
Ph: (215) 675-5200
Fx: (215) 682-8689

Device trade/proprietary name:

ISOLETTE® Infant Incubator

Device common/usual/classification name:

Infant Incubator

Classification:

General Hospital
21 CFR 880.5400
Incubator Neonatal, 80 FMZ, Class II

Performance Standards:

None applicable.

Predicate (Current) Device:

K960980 ISOLETTE® Infant Incubator Hill-Rom Air-Shields

Device Description

The Hill-Rom Air-Shields ISOLETTE® Infant Incubator design provides a thermally stable and nurturing environment for the newborn infant. It is to this end that the incubator has been designed to provide a controlled environment for the baby, one in which the temperature, humidity and level of oxygen can be maintained within desired limits as prescribed by the care giver.

The incubator is comprised of 3 main elements namely, the hood, shell and stand. Together they measure H56in x W38in x D23in. One of the stand options allows the user to raise and lower the unit

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ISOLETTE® Infant Incubator

The incubator is comprised of 3 main elements namely, the hood, shell and stand. Together they measure H56in x W38in x D23in. One of the stand options allows the user to raise and lower the unit to a convenient working height. This stand has a travel of 8.0in giving a height range of 51.5in up to 60in. The foam based mattress that measures 16in x 31.5in positions centrally within the confines of the hood. The mattress can also be raised at the head and foot end to a maximum incline of 12°. This is achieved by rotating knobs that are located on each end of the incubator shell.

The hood is made of a clear acrylic to permit clear visibility of the baby yet provide isolation for the baby. The hood comprised of 6 access ports gives access to the baby without compromising the thermal environment. Four of the access ports (two on the front and two on the rear) allow for regular access by the caregiver. The other two access ports are in the form of iris ports with are used primarily for ventilator tubes and monitoring cables to be channeled into the hood to the baby. In addition to the port doors there is also a full width access panel on the front and an optional rear access panel that affords total access to the baby. Withdrawing the mattress towards the caregiver can enhance access even further. The mattress extends 11in outside of the incubator hood. To provide additional thermal insulation for the baby the hood incorporates a double wall on the front and the rear walls. Air is passed between these walls with the purpose of raising their temperature and providing greater insulation against the temperature outside of the incubator.

The shell of the incubator houses the electronics that controls the environment. Located beneath the mattress is the heater that warms the air that is circulated within the hood of the incubator. A DC motor drives the impeller drawing fresh air in through a micro air filter and pushing it over the heater and thus into the incubator hood. The air circulates in the hood by passing through the front and rear inner walls and returning via a vent in the right had side of the deck. While fresh air continues to be drawn in through the fresh air inlet, the majority of the air is re-circulated. The fresh air intake into the hood ensures an adequate throughput of fresh air that keeps CO_2 build up to a minimum.

The temperature inside the infant compartment is controlled by selecting an air temperature in the range of 20-39°C via the control panel. Once selected a temperature thermistor located inside the hood monitors the temperature. The thermistor is part of a servo control loop that continually update the controller which in turn adjusts the output of the heater to maintain the desired temperature within the infant compartment. An alternate mode of operation is also available that controls the baby's skin temperature. This mode is adjustable over the range of 34-38°C. In this mode, the air temperature is varied in order to optimize the skin temperature. This is achieved by means of a skin temperature probe being placed on the baby's abdomen.

Depending on the age of the patient it is sometimes necessary to provide supplemental humidity. The incubator provides the ability to raise the level of humidity inside the infant compartment from 30-95%. A reservoir is located inside a compartment on the front of the main shell. The reservoir holds up to one liter of distilled water that will typically generate humidity for up to 24 hrs. The level of humidity is selected via the main control panel. The water from the reservoir enters a heater chamber that heats the water to a level required for vaporization. A pressure build up inside the heater

chamber allows the moisture to enter the air stream and hence elevate the level of humidity inside the infant compartment. The level of humidity in the hood is controlled by way of a servo control system that is linked to a %RH sensor located inside the hood.

The final element of the environment that can be controlled is the oxygen level. The oxygen level in the hood can be controlled at a level between 21-65%. Oxygen is selected in the same way as temperature and humidity via the main control panel. Oxygen is supplied via a high-pressure hose into a pneumatic module located on the rear of the incubator shell. The oxygen can be supplied at a pressure up to 150 psi. When it enters the pneumatic module the gas pressure is stepped down to a working pressure of 10 psi. The flow of gas is also inhibited by a solenoid valve which is sin the "normally off" position. The rate of flow of gas into the infant compartment is determined by the opening and closing of the valve which is part of a servo control loop linked to dual sensors located inside the infant compartment. One of the sensors monitors while the other controls. Failure in sensor operation is detected by continually cross referencing the output of each sensor against each other.

One more function performed by the incubator is displaying the baby's weight. An optional scale platform sits inside the mattress tray. Contained within the platform are the load cells. The weight is recorded and displayed on the main display. The scale weighs to an accuracy of 2 grams up to 2000 grams and 5 grams up to 7000 grams and has a display resolution of 1 gram.

The main display of the Hill-Rom Air-Shields ISOLETTE® Infant Incubator is available as either a LCD or EL format. It forms the focal point for all data displayed and control change entries. It displays air temperature, two skin temperatures, temperature set point, weight, oxygen %, humidity % and the respective set points. The main display also has a trend screen that will trend all of the parameters as well as the baby's weight. The trend displays the changes in a real time format as well as displaying past data over a 1, 2, 4, 8, 12 and 24 hour period. The only exception to this is the weight that is trended over a 7 day period. The parameter displayed is selectable via a menu.

Each control function (air and skin temp and oxygen) has preset set point alarms to alert the user of changes in control state that may affect the baby. In addition there are alarms for elevated air temperature, air flow failure, sensor failure, power failure, low water, hi/lo oxygen and microprocessor/control system failure.

The hood and shell sit on a pedestal stand that is sized for a comfortable working height for the attending caregiver. The stand allows the incubator to be moved around the nursery. It also accommodates storage modules that are swivel drawers. An optional IV pole and monitoring shelf also attach to the stand and can be moved with the incubator. Two versions are available; a fixed height and a variable height. The latter allows the incubator to be adjusted to the optimum working height for the user.

510(k) Summary
Hill-Rom Air-Shields
ISOLETTE® Infant Incubator

Intended Use:

The Hill-Rom Air-Shields ISOLETTE® Infant Incubator is designed to care for the smaller premature baby as well as the healthier full term baby. It does this by providing a controlled environment, one in which the baby can be provided with the necessary care as well as being left undisturbed in the security of the incubator.

It is to this end that the product can be used in any department of the hospital that provides neonatal and infant care. One would typically expect the ISOLETTE® to be used in the NICU/SCBU (Neonatal Intensive Care Unit and / or the Special Care Baby Unit). The design lends itself to all levels of care in the NICU making it suitable for use in level I, II, III and IV where applicable. Other departments would include the Step Down Nursery, Newborn Nursery and pediatrics.

The ISOLETTE® is marketed worldwide.

The subject device and predicate device in this submission are substantially equivalent.

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ISOLETTE® Infant Incubator

Description of Modifications:

The modifications that are the subject of this submission are summarized below:

a. Redesign of system controller.
   i. New hardware with same functionality.
   ii. New software with same functionality.
   iii. Additional hardware "Watchdog".
   iv. Enhanced front panel with keypad lock.
   v. One controller for all voltages/language configurations.
   vi. Test diagnostics added in software for ease of service.

b. Change of manufacturing location of controller.
   i. Controller will be manufactured by:
      - Hill-Rom Air-Shields, Hatboro, PA.
      - Da Tech Corp., Warminster, PA.

c. Addition of thermal cutout to heater assembly.
   i. A thermal cutout has been added to the heater assembly to enhance the ability of the system to detect and prevent excessive thermal conditions.

d. Redesign of airflow detection system.
   i. The airflow probe has been replaced with an impeller movement detection circuit, which incorporates the use of hall-effect devices.

e. Redesign of sensor module.
   i. Changed humidity sensor to a "Vaisala" sensor that does not require calibration.
   ii. Replaced fan with one using hall-effect sensors for motion detection (previously optical).
   iii. Housing changed to incorporate "guides" to aid in probe insertion.
   iv. Improved labeling for ease of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2000

Mr. James G. Carpenter
Director, Regulatory Affairs
Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, Pennsylania 19040

Re: K001242
Trade Name: Isolette Infant Incubator, Model C2HS
Regulatory Class: II
Product Code: FMZ
Dated: April 15, 2000
Received: April 18, 2000

Dear Mr. Carpenter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: ISOLETTE® Infant Incubator

Indications for Use:

Effective temperature management is imperative to the development of the premature baby. The ISOLETTE® Infant Incubator incorporates a unique bi-directional air flow to help reduce radiant heat loses from the infant by warming the inner hood surface. The Hill-Rom Air-Shields patented Air Curtain has been incorporated into the ISOLETTE® Infant Incubator to reduce temperature fluctuations within the incubator when the access panels are opened. With the Humidity Module installed, operational evaporative heat losses are minimized. With the installation of the optional Oxygen control system, the Oxygen level within the infant compartment can be monitored and maintained.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

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